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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,765	08/21/2003	Craig A. Rosen	PS736	7999

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EXAMINER	
SALMON, KATHERINE D	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/644,765	ROSEN ET AL.	
	Examiner	Art Unit	
	Katherine Salmon	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2003*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-10, and 21, drawn to an isolated nucleic acid molecule, a recombinant vector, and a recombinant host cell, classified in class 536, subclass 23.1, class 435, subclass 320.1, and 435 subclass 325, respectively.

   II. Claims 11-12, 14-16, and 23 drawn to a polypeptide, classified in class 530, subclass 300.

   III. Claim 13, drawn to an isolated antibody, classified in class 424, subclass 130.1.

   IV. Claim 17, drawn to a method for preventing, treating, or ameliorating a medical condition comprising administering a polypeptide, classified in class 514, subclass 21.

   V. Claim 18, drawn to a method of diagnosing a pathological condition comprising determining the presence or absence of a mutation in the polynucleotide, classified in class 435, subclass 6.

   VI. Claim 19, drawn to a method of diagnosing a pathological condition by determining the presence or amount of expression of the polypeptide, classified in class 435, subclass 5.

VII. Claim 20, drawn to a method for identifying a binding partner to the polypeptide, classified in class 435, subclass 5.

VIII. Claim 22, drawn to a method of identifying an activity in a biological assay, classified in class 435, subclass 70.1.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions (I and V) and (II, IV, VI, VII, and VIII) and (III) are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group (I and V) is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptides of Group (II, IV, VI, VII, and VIII) is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. The antibodies of Group (III) is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of Groups I-VIII can be used in materially different processes, for example the DNA of group (I and V) can be used in hybridization assays, the antibodies of Group (III) can be used in immunoassays, and the polypeptides of Group (II, IV, VI, VII, and VIII) can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each group are different. Therefore, the inventions of groups (I and V) and (II, IV, VI, VII, and VIII) and (III) are patentably distinct from each other. The search for each of groups (I and V) and (II, IV,

VI, VII, and VIII) and (III) presents a serious search burden, as the searches for each are not coextensive in scope. The inventions have different status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides, which would not have described the polynucleotides. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide but spoke to the gene. A polypeptide and an antibody that binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies. Furthermore, antibodies, which bind to an epitope of a polypeptide of group, may be known even if the polypeptide is novel. Searching, therefore is not coextensive.

2. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the nucleic acid of Invention I can be used in a method of diagnosing a pathological condition comprising determining the presence or absence of a mutation in the polynucleotide or can be used

in a method of a gene expression array. The search for each invention presents a serious burden, as the searches for each are not coextensive in scope. Art relating to the nucleic acid molecules of Group I would not necessarily provide descriptive information on the methods of diagnosing a pathological condition comprising determining the presence or absence of a mutation in the polynucleotide.

3. Inventions II and (IV, VI, VII, VIII) are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide of Invention II can be used in a method for preventing, treating, or ameliorating a medical condition, a method of diagnosing a pathological condition, a method of identifying a binding partner, or a method of identifying an activity in a biological assay or the polypeptide can be used in a method of SNP genome screening. Art relating to the polypeptide would not necessarily provide descriptive information on the method for preventing, treating, or ameliorating a medical condition, a method of diagnosing a pathological condition, a method of identifying a binding partner, or a method of identifying an activity in a biological assay

4. Inventions IV, VI, VII, and VIII are distinct methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions share a common step wherein they all use polypeptides. Beyond this commonality, however, the methods are distinct from one another because they require different process steps, reagents, and analyses for their completion. For example, a method for preventing a medical condition does not require the same steps as a method of identifying a binding partner to the polypeptide. The reagents, reaction conditions, and reaction parameters required to use in each group are different. The search for IV, VI, VII, and VIII presents a serious search burden, as the searches for each are not coextensive in scope.

5. Additionally, the Inventions named above are subject to **further restriction**. For Invention I, V, pick a specific polynucleotide and indicate a specific SEQ ID No, ATCC deposit No. For Invention II-IV, VI-VIII, pick a specific polypeptide and indicate a specific SEQ ID No. This is **NOT an election of species**. The nucleic acids are drawn to a structurally distinct nucleic acid molecule. The polypeptides are drawn to a structurally distinct nucleic acid molecule. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide and polypeptide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141. By statute, "[I]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121.

Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant...to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). It is noted that searching more than one of the claimed patentably distinct sequences or combination of in the alternative, represents a serious burden for the office. It is noted that any claim not drawn to a particular sequence or polymorphisms will be examined as broadly as it is claimed. Additionally, applicant should amend the claims to reflect the election.

6. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because inventions I-VIII require different searches that are not coextensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Katherine Salmon 5/11/2006

Katherine Salmon
Examiner
Art Unit 1634

Jehanne Sitton

JEHANNE SITTON
PRIMARY EXAMINER
5/11/06